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The Role of Analytics in Transforming Healthcare

By John Russell

CONTRIBUTING AUTHORS:

Brett Davis — Senior Director, Personalized Healthcare, Oracle Health Sciences

Karen Jaffe — Director, Safety Analytics, Oracle Health Sciences

Jonathan Palmer — Director, Clinical Development Analytics, Oracle Health Sciences

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> *"To wrest from nature the secrets which have perplexed philosophers in all ages, to track to their sources the causes of disease, to correlate the vast stores of knowledge, that they are quickly available for the prevention and cure of disease — these are our ambitions."* — *Sir William Osler, 1906*[i]

Modern healthcare has long held grand goals for itself, perhaps never stated more boldly and succinctly than in the quote above from Sir William Osler, a seminal thinker, teacher, and practitioner in modern medicine. Today, advancing biomedical science —including the proliferation of the 'vast stores' of data — seems on the verge of bringing much of Osler's optimistic vision into practical fruition.

Twenty-five years of unprecedented expansion in scientific knowledge are revealing the underlying causes of disease while technology breakthroughs in imaging, genomics, proteomics, diagnostics and other disciplines promise to usher in a wave of new innovation in the prevention and cure of disease. Many speculate we are on the verge of a new era in healthcare where the triumphs of the last quarter century in medical innovation will result in improved quality of life, increased life expectancies, and the eradication of horrible diseases such as cancer, Alzheimer's and Parkinson's.

Yet against this backdrop of remarkable innovation, global healthcare systems are reaching breaking points that many believe are unsustainable. Developed nations are struggling with soaring costs, inconsistent care quality, and inaccessibility to timely, efficient care for many of its citizens. That's prompted many nations to seek fundamental health system reforms to change the perceived unsustainable trajectory.

Consider the bleak picture painted by the U.S. Office of Management and Budget (OMB), "The United States spends over $2.2 trillion on health care each year—almost $8,000 per person. That number represents approximately 16 percent of the total economy and is growing rapidly. If we do not act soon, by 2017, almost 20 percent of the economy—more than $4 trillion—will be spent on health care." [ii] Of course, the healthcare challenge is worldwide and developing countries confront even more fundamental challenges.

Most problematic is that so much of what is spent on healthcare doesn't produce health benefit. The most commonly cited example is that major classes of drugs only work in 30-60% of the people they are administered to[iii]. Indeed, OMB has estimated that $250B to $325B[iv] is spent annually on unwarranted care. Comparable inefficiency and waste also are found throughout drug discovery and clinical trial activities.

The result is that global health and healthcare systems stand at a critical juncture and the frequent conclusion reached by many observers is that healthcare is either headed towards restrictive rationing or that healthcare systems will be simply unable to consume and deliver medical innovation because it's too expensive.

In fact, the real solution is likely to be multi-faceted and combine dramatic and nuanced change. New business models around personalized medicine and the rise of comparative effectiveness-driven reimbursement hold great promise for restraining cost growth and improving outcomes. Indeed, outcomes data is likely to become much more important and linked directly to clinical and research data so that the health science value chain starts to look and act more like a truly connected enterprise.

Secondary Use of Health Data

Analytics Has Value Across the Healthcare Ecosystem

Healthcare Providers
- Clinical quality initiatives and reporting
- Operational efficiencies
- Financial performance management
- Pay-for-performance initiatives

Pharmaceutical / Biotechs
- Comparative effectiveness
- Adaptive trials to support personalized medicine
- Consumer and physician engagement and decision support

Academic Medical Centers
- Translational, clinical and comparative effectiveness research
- Collaborative and extra-enterprise research

Public Health
- Disease surveillance
- Comparative effectiveness and clinical utility studies

Under this new paradigm, successful organizations will be differentiated not by the existence of core transactional electronic systems, but by their ability to manage, integrate, analyze and leverage clinical, financial, claims and other biomedical information from across their enterprise and external to their enterprise. Leaders will successfully use that information to improve quality of care, understand what value means in healthcare and accelerate the translation of research discoveries into practice by providing physicians, researchers, administrators and consumers with actionable data at the right time and place

"We need to take advantage of this perfect storm of data," says Brett Davis, Senior Director, Health Sciences, Oracle. "If we aggregate all the data that's being generated in multiple silos across the healthcare ecosystem and use it in the right context, I believe, we won't have to sacrifice innovation at the expense of addressing the cost-quality challenges healthcare systems face."

"I would argue this is a data aggregation and analytics challenge. We now have systems in place where if you aggregate from multiple disparate systems you can begin to understand what works and what doesn't work from a clinical effectiveness as well as cost perspective," notes Davis.

In other words, the secondary use of data captured in transactional systems across the healthcare ecosystem—electronic health records, claims / billing systems, CTMS, research databases, personal health records—will be essential to enabling and accelerating a new paradigm of personalized healthcare. This information-based transformation of healthcare to a more personalized healthcare paradigm can be visualized using the "learning healthcare" framework," championed in an Institute of Medicine Study in 2007 (See Fig. 1[v]). In this paradigm, the core transactional systems become a necessary but insufficient step to support a rapid learning, value-based, personalized healthcare paradigm.

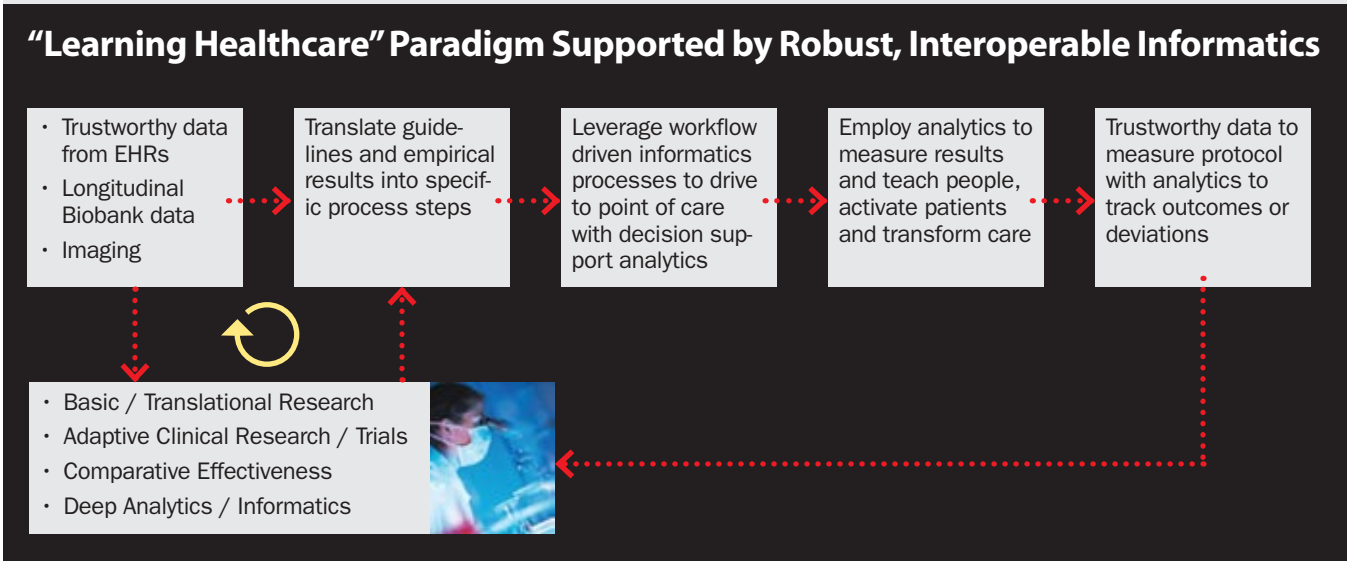
However, today's healthcare application deployments and attempts at integration infrastructures typically fall short in their ability to support this new paradigm. They fall short on multiple fronts. Often, they not only fail to collect the necessary information in the right context, but also fail in their ability to provide the necessary linkage between financial, operational, research and clinical processes.

In today's multi-vendor transactional system environment, integration standards and repeatable processes are critical to providing adequate data management capability. Building the right infrastructure to support data collection, integration and transformation is essential to establishing a strong foundation that supports the types of analytics solutions that will enable the transformation described above.

Oracle responded to the fundamental shifts occurring in healthcare two years ago by forming the Health Sciences Global Business Unit. It was clear then that healthcare and life science were necessarily converging, and that tighter linkages and increased information flow between research, clinical trials, diagnostics, and healthcare delivery would be required for meaningful progress. Today, 20 of the 20 top pharmas and 14 of the 15 top U.S. hospitals run Oracle.

One of the key missions for the new Health Sciences business unit is to drive strategy and product development around the interoperable use of analytics throughout the health sciences value chain and ecosystem. It was increasingly clear that deep enterprise analytics could be transformative for the

FIGURE 1



industry in multiple contexts. Today, that strategy is in place and Oracle's Health Sciences' core analytics platforms are rapidly becoming available.

At the core of this strategy is Oracle's Enterprise Healthcare Analytics (EHA), introduced at HIMSS Conference & Expo in March 2010. EHA integrates data from electronic medical records, clinical departmental systems, patient accounting, ERP, research, and other source systems to help providers rapidly and cost effectively unlock value from their clinical and operational data. Underlying EHA is Oracle's Healthcare Data Warehouse Foundation, a comprehensive enterprise data model, which in many ways is the cornerstone of Oracle's entire analytics strategy throughout Health Sciences. The model includes an expanding list of more than 1,000 entities and 12,000 attributes spanning the clinical, financial, operational, and research domains.

"There are many reasons we took this approach," explains Davis. "If you look at the healthcare IT market today, there are many data models. Typically they sit underneath transactional applications and are tuned for specific transactional workflows. But the relationships between the financial, operational, clinical, and research information is really what's transformational in our view, and you can't get that from any single transactional system or set of transactional systems. You really need an integrated view across disparate transactional systems, and that calls for a robust, enterprise model that is optimized for analytics, vs. transactional, purposes."

"You can think of the Oracle approach as productizing a data model versus having it be a one-off custom built asset, which is how most data warehouses get built in healthcare today. By locking down and creating a core data model you now can begin to productize much of the ETL (extraction, transform load) pulling the source data systems out. That's a very, very expensive step, cost prohibitive to all but the top ten or 15 health systems in the country."

Productizing the data model also makes it easier to attract and create an ecosystem of analytics partners who build applications to that data model and EHA platform. Oracle announced five initial partners including, for example, Quantros, which is used roughly by 2000 hospitals for quality, accreditation & compliance, and risk management. By adopting Oracle's enterprise data model, notes Davis, data collection from multiple diverse systems—previously a manually intensive activity—can be automated. Quantros can readily access and format data from the Oracle warehouse. "That's one example of a partner and one example of why you productize the data model," says Davis.

Vigilanz, which monitors patients and detects

adverse events such as hospital-acquired infection, is another early partner. Previously a fair amount of custom work was required to get data into the proper format for these types of solutions; now much of that works is avoided. Two other early partners are InforSense (IDBS), which is building translational research applications to the Oracle model, and Outcomes Sciences, which is the leader in patient registries.

"Oracle's Enterprise Health Analytics strategy begins to lower the center of gravity or 'democratize' if you will the ability for most of health care to take advantage of enterprise analytics versus spending millions of dollars to build a one-off custom, data warehouse," says Davis.

As part of the Health Sciences analytics strategy, Oracle is also developing its own applications, and the first one announced is Oracle Operating Room Analytics. ORs typically account for a high fraction of profit and expense in hospitals, up to 50% in many instances. The new analytics application provides critical decision support around supply chain costs, staffing, quality outcomes, surgeon performance and many other services that would not be possible without an integrated enterprise view of the enterprise. Effective use of OR analytics can have an immediate financial impact for a healthcare system. Over time Oracle will steadily add more Health Sciences analytics applications.

Another advantage the adoption of Oracle's well-documented, comprehensive data model is that is becomes much easier for internal developers or consulting partners to build business intelligence applications on top of the model.

On balance, says Davis, "If you look at our strategy, it's really about bringing enterprise health analytics to the provider market and bringing it down to a cost point where most of healthcare could adopt it to drive the innovation and transformation promised by the healthcare IT industry. The adoption of the core clinical and financial systems in healthcare is really a necessary yet insufficient step in achieving real health system change. It will be the secondary use of that data to drive clinical quality, operational efficiencies and new research discoveries to market that will really change healthcare."

There are certainly other approaches to creating analytics warehouse platforms and as with all technology choices, there are tradeoffs. Fundamental to the Oracle approach is ensuring that the data brought into the analytics environment is semantically normalized, which means additional deployment steps. "You cannot escape the "garbage in, garbage out" problem. We have focused much of our effort on the "plumbing" to get the data aggregated, normalized, cleaned, and leveraging the industries terminology services, to make sure that data from one system and data from another system, once its aggregated, are consistent and credible," says Davis. "I think that's the major difference from other approaches on the market today. If you skip that important step as a health system, you just end up wasting money and effort, and worse damaging, credibility with clinicians, researchers and executives."

Possessing an EHA platform will provide integrated delivery networks with novel competitive advantages, says Davis: "Let's say you're a five hospital health system that has 40 percent of the market and you've invested in this rigorous, well annotated, believable analytical data store. Then put yourself in the shoes of the VP of research or head of clinical development at a major pharma. You are facing challenges around innovation, fundamental business model changes like moving away from blockbuster drugs to personalized therapies, and simultaneously being pressed by regulators on post-market surveillance issues, and dealing with new comparative effectiveness regulations.

"Your head is swimming, but common to all of those challenges is the need for access to longitudinal information about what happens in a 'real-world' healthcare setting. If you're the health system that has this robust analytics environment that aggregates all that data that people need, in a very secure environment, your ability to sit down and form a novel partnership with a pharma/biotech has just gone up many-fold and put you in an interesting spot versus other health systems who may have interesting data, but don't have the longitudinal nature of that data captured in an analytics environment where value can be extracted. It begins to create an interesting market opportunity for a health system in terms of ethical partnerships that perhaps they couldn't have contemplated before."

CLINICAL TRIAL ANALYTICS

Few activities have proven as difficult to manage as clinical trials. They are complicated, often conducted at far-flung sites, involve clinicians, patients, sponsors, and are subject to tremendous scientific, operational, and logistic challenges, any of which can delay or derail a trial. For the few compounds that successfully navigate the Phase 1 through Phase 3 pivotal studies, the average journey is about five years. Many more compounds fail than succeed.

Recently the high cost of trials in developed economies and difficulty with recruiting patients for trials have prompted drug makers to push clinical trials into regions where the costs can be substantially lower. However, the push into lower cost geographies can bring additional challenges: critical IT infrastructure and important clinical trial policy machinery (e.g. obtaining IRB approvals) are often less mature; desirable sub-populations for personalized medicine may or may not be present; and supply chain logistics become difficult to manage.

From an enterprise analytics perspective, pharmas and biotechs are struggling to get decent analytical and decision-making across their systems. Currently many of these companies tend to have reporting systems attached to all the transactional applications. Frequently this entails use of very many disparate technologies and obtaining a cohesive integrated view is virtually impossible.

"If they ask a simple question such as how many subjects have been enrolled in a trial, they often get four answers and they are all different," says Jonathan Palmer, Director, Product Strategy, Clinical Development Analytics. When you drill deeper, he notes, it often turns out that the data from these diverse applications are ultimately manually, and painstakingly, integrated into performance management reports by dedicated teams of Excel wizards. "Often these Excel spreadsheets are completely awash with highly complex macros that only one person in the business understands."

Oracle introduced Oracle Clinical Development Analytics (CDA) last November, the vanguard of its extensive analytics roadmap. It is the first version of an integrated analytics warehouse platform to span the clinical trial and safety space that's sourcing data from typical clinical development systems such as EDC and CTMS solutions. The central idea is to provide a consistent unified view of reporting across the organization.

Prepackaged content, primarily around the EDC at the moment, is an important distinguishing feature. "We are unique in having this content. In this release it's about things like how many eCRFs have been processed, how many need to be processed, and cycle times around that. There are also some metrics around data queries, such as how many are open, how many are closed," says Palmer. "We're building different views of data to help organizations with the whole process of the clinical trials starting at the feasibility area and looking into planning, setting up the trial, start-up, and of course a big area is the overall recruitment space. How are we doing in terms of plan versus actual versus the forecast, etc."

A key strength of the Oracle approach is the ease with which CDA can serve multiple constituents including end users, operational users at the data management level or at the clinical monitoring level, rolling up to heads of clinical and senior executives. The view of the data is consistent, just the level of aggregation and granularity of the data varies. This ability to provide consistent, appropriate views to different layers in the organization has historically been difficult to accomplish. More prepackaged content will be added over time, and future candidates include financial and drug supplies management capabilities.

The time-to-deploy and time-to-benefit for CDA are surprisingly short. Three-to-six months should be typical for deployment, says Palmer, and organizations would see benefits immediately. Both pharmas and CROs could quickly tackle some of their major clinical trial operations management issues. Here are just two examples:

- Many pharma today rely entirely on their CROs for clinical trial status reports and management metrics. A single unified warehouse platform would give them transparency across all of their studies whether they are done in house or out of house, says Palmer.
- CROs report most clients ask for similar reports with small differences that consume valuable re-

sources to create and cause delay. Having built the warehouse and infrastructure, creating new reports could be done in minutes and easily customized.

Moving forward the Oracle roadmap for Clinical Development Analytics includes developing both predictive and simulation tools starting with subject recruitment and moving to drug supplies at a later date. Being able to accurately forecast your recruitment is going off track and spotlighting how could allow sponsors to act more quickly to find a remedy. Similarly, a simulation tool could inform initial trial planning as well as corrective strategies when things go awry.

"So let's say the predictive tool looking three months ahead indicates your trial is in trouble, that you won't enroll enough patients," says Palmer. You could use the simulation tool to ask, "What if we added more sites in China and in Denmark? What would that really do for us?"

"You could then say, we've got a huge potential population of patients which we could enroll to meet our recruitment targets, but in China there's a problem because it takes a long time to get a study operational for example, whereas in Denmark you can get the ethics approval very quickly, but actually there are fewer subjects. You put that type of information into a model and do what-if simulations to develop a plan to get back on track," says Palmer.

SAFETY ANALYTICS

As in healthcare and clinical development, Oracle is fashioning an extensive roadmap around safety analytics and tackling both traditional performance management as well as risk identification and corroboration.

Within safety three problem areas are being targeted:

- **Workflow Performance.** This is traditional operations management, dealing with issues such as workload balancing—are more people required, for example, —and workflow efficiency generally. Operations efficiency is major concern and contributor to cost in safety.
- **Regulatory Compliance.** Activities around submissions and their progress are examined and indicators such as the number of submissions expected, the percent on time, the potential for delay with submissions, are flagged.
- **Quality.** "It dovetails somewhat with performance," says Karen Jaffe, Director, Product Strategy, "but relates to quality of case entry and having to reroute cases and so forth as a result of case quality. Case quality, for example, can become a concern with the overall productiveness of Biopharmaceuticals and CROs alike in processing AEs."

Risk identification and corroboration represents a slightly different use of analytics. More attention is being paid to pharmacovigilance generally by regulators and companies are being pressed by the anticipation of CIOMS VIII to deploy better tools and tracking mechanisms to identify and manage products that have most adverse events associated with them. Developing risk profiles for a particular product and product event combinations isn't trivial. Such requirements have far reaching impact throughout organizations, and helping companies deal with PV issues and executing on REMS or RMPS will be a significant enhancement to Oracle's roadmap moving forward. There is a growing pressure to demand more active risk identification throughout the lifecycle of a product through a cross-functional team of product stewards.

"We are giving pharma companies the opportunity to not only gather and analyze the data within their own database, but also from external data sources to allow them to ensure that the risk identified or potential risk identified with using analytics with their own data source can be corroborated with external data sources as well," Jaffe says.

CONCLUSION

The use of well-defined and well-integrated analytics throughout the healthcare value chain can be transformative. Given the immense size of the data challenge, the distinctness and geographic spread of many healthcare-related activities, and the fact that so many healthcare activities are conducted by different companies and organizations which must interact with each other, there is really no other way to provide operations management tools necessary to deliver personalized medicine and to control spiraling costs. Oracle's strategy—built upon

Enterprise Health Analytics and Health Data Warehouse Foundation—provides a powerful, practical, and extensible approach to delivering the IT analytics infrastructure required to confront the worldwide healthcare challenge.

Sharing many of the data challenges and opportunities faced by Healthcare, the Life Sciences industry remains focused on delivering new, innovative therapies and solutions to patients in a cost effective, timely and safe way. With spiraling R&D costs, new methods such as adaptive trials, and never ending need for deep pharmacovigilance, the Life Sciences companies that effectively use analytics to explore, monitor and optimize their business will rapidly become the new leaders.

Footnotes:

[i] Chauvinism in Medicine, in Aequanimitas, p 267

[ii] Transforming and Modernizing America's Health Care System, OMB, 2010, http://www.whitehouse.gov/omb/fy2010_key_healthcare/

[iii] The Case For Personalized Medicine, 2006, Personalized Medicine Coalition http://www.personalizedmedicinecoalition.org/communications/TheCaseforPersonalizedMedicine_5_5_09.pdf

[iv] Multiple Sources: The Dartmouth Atlas of Health Care (http://www.dartmouthatlas.org/); Thomson Reuters Research (http://www.ncrponline.org/PDFs/Thomson_Reuters_White_Paper_on_Healthcare_Waste.pdf)

[v] The Learning Healthcare System. Workshop Summary, Institute of Medicine, March 2007, http://www.iom.edu/Reports/2007/The-Learning-Healthcare-System-Workshop-Summary.aspx